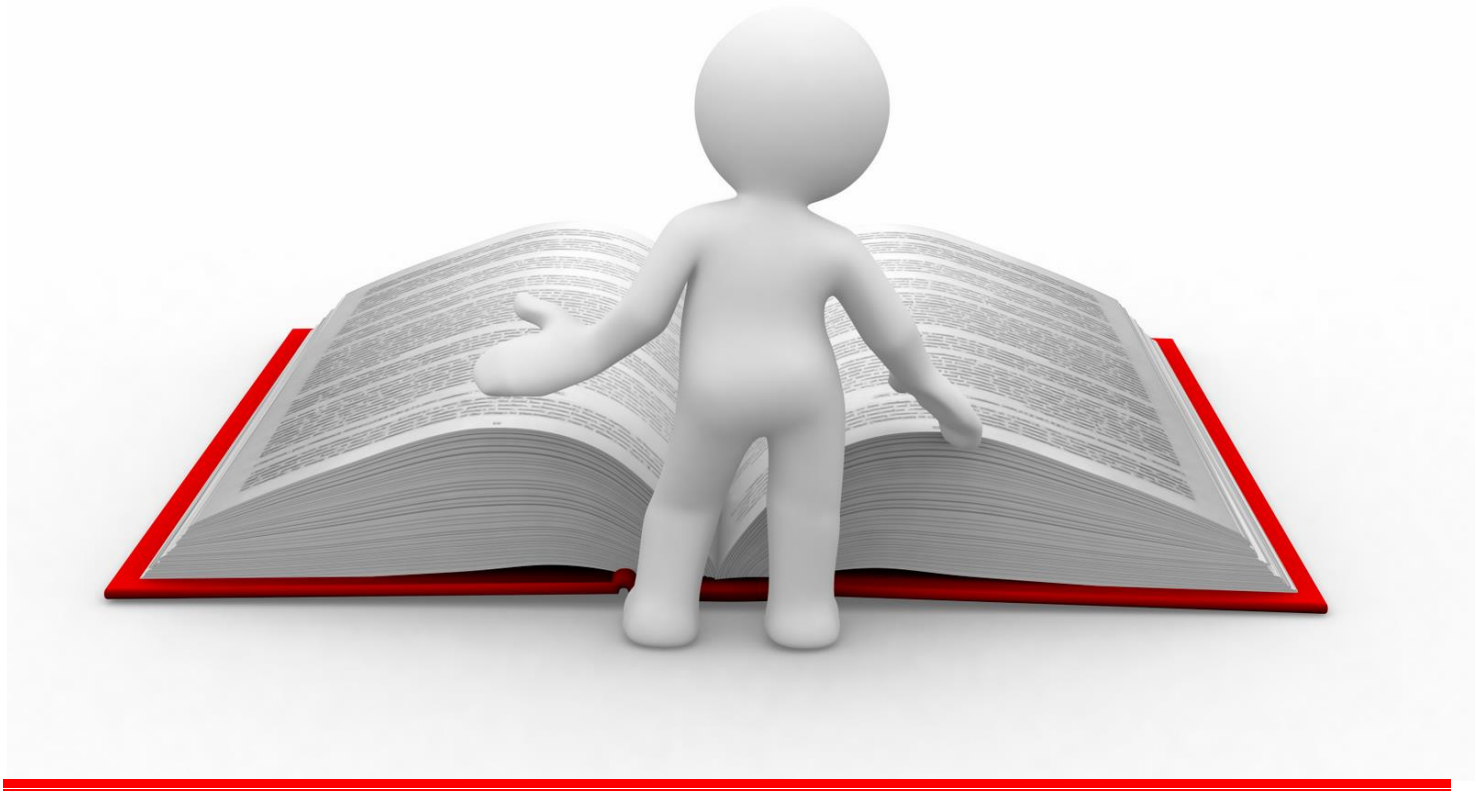

2018-2019 VFC Provider Handbook

Tennessee Immunization Program (TIP)

Vaccines for Children (VFC) Program

Tennessee Department of Health| CEDEP | TIP

Revised: August 1, 2018

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Introduction

The Tennessee Immunization Program (TIP) is in the Tennessee Department of Health (TDH), under the Communicable and Environmental Disease Services and Emergency Preparedness (CEDEP) division.

Our Mission:

To protect people of all ages in Tennessee from vaccine-preventable diseases.

Our Vision:

A Tennessee free of vaccine-preventable diseases.

Core Values:

- Credibility – Honest and accurate in all we do.
- Innovation – Creative and responsive on changing times.
- Accountability – Serve customers with integrity and compassion.

The Vaccines for Children Program (VFC) is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated due to inability to pay. TIP provides federally purchased vaccine to eligible health care providers enrolled in the VFC Program. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are routinely or permissively recommended by the Advisory Committee on Immunization Practices (ACIP), as published in the CDC's Recommended Immunization Schedules for Persons aged 0 through 18 Years (https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html).

VFC Program Benefits:

- Provides cost-savings to states and territories through bulk purchase of vaccine at lower prices using federal contracts, and eliminates state-to-state differences in price.
- Reduces referrals of children from private providers to local health departments (LHDs) for vaccination.
- Saves VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminates vaccine cost as a barrier to immunizing eligible children.

Acronyms

ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, eXchange
CDC	Centers for Disease Control and Prevention
DDL	Continuous temperature monitoring device, or “Digital data logger”
FQHC	Federally Qualified Health Center
EHR	Electronic Health Record
HL7	Health-Level 7 (the standards for electronic transmission of health data)
HRSA	Health Resources and Services Administration
LHD	Local Health Department
PIN	Provider Identification Number
RHC	Rural Health Center
RIR	Regional Immunization Representative
TE	Temperature Excursion
TennIIS	Tennessee Immunization Information System, or “Immunization Registry”
TIP	Tennessee Immunization Program
DHHS	Department of Health and Human Services
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering and Management System (within TennIIS)

TIP Contact Information

VFC Enrollment and Operations – Contact for general VFC enrollment questions or to update designated Primary and/or Back-up VFC Contacts.

Phone:	(800) 404-3006
Fax:	(615) 401-6831
Email:	VFC.Enrollment@tn.gov
Available:	Monday thru Friday 7:30am to 4:00pm CDT

VFC Quality Assurance (*Effective 10/2018, incorporated into* ***Program Improvement and Evaluation Team***) – Contact for vaccine storage and handling issues, temperature excursions, AFIX or compliance questions or concerns.

Phone:	(800) 404-3006
Fax:	(615) 401-6829
Email:	VFC.Help@tn.gov Temperature.Health@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

Vaccine Management – Contact for vaccine supply issues, including ordering, inventory, reconciliation, returns, VOMS training and VOMS user permissions

Phone:	Public Health Departments - (615) 532-8511 All other VFC Providers – (800) 404-3006
Email:	TennIIS.VOMS@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

TennIIS Help Desk – Contact for general TennIIS assistance

Phone:	(844) 206-9927
Email:	TennIIS.Help@tn.gov
Available:	Monday thru Friday 7:00am to 6:00pm CDT

TennIIS Facility Registrations and User Updates – Contact to register a facility in TennIIS, to add or inactivate users, or to apply TennIIS user permissions

Phone:	(615) 741-7207
Email:	TennIIS.Registration@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT
Website:	https://www.tennesseeiis.gov

TennIIS Training – Contact for information about TennIIS training options

Phone:	(844) 206-9927
Email:	TennIIS.Training@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

TennIIS Electronic Data Trading and Meaningful Use – Contact about establishing an interface between your Electronic Health Record (EHR) and TennIIS

Phone:	(615) 253-1360
Email:	TennIIS.MU@tn.gov
Available:	Monday thru Friday 7:30am to 4:00pm CDT

VFC Fraud/Abuse Prevention – Contact TIP to report concerns about misuse or mishandling of VFC vaccines. Reports may be anonymous; all are confidential.

Phone:	(800) 404-3006
Fax:	(615) 253-3279
Email:	VFC-Fraud.Health@tn.gov
Available:	Monday thru Friday 7:30am to 4:00pm CDT

VFC Program Resources for VFC Providers:

TDH TIP website	Documents and forms referenced in the VFC Provider Handbook can be found under *VFC Guidance & Toolkits* on the TIP website at: http://www.tn.gov/health/cedep/immunization-program.html.
TennIIS Document Center	Important VFC communications are sent to all VFC contacts and copies are posted in the Document Center, accessible on the main TennIIS page after a user logs in.
TennIIS Homepage	The public (non-secure) TennIIS homepage has links to TennIIS training guides, videos, webinars, and other helpful resources: https://www.tennesseeiis.gov.

1. Enrollment

1.1 Who May Enroll

To participate in the Tennessee VFC Program, a healthcare provider must have an active, unencumbered medical or advanced nursing practice license in the state of Tennessee. In addition to providing practice information, Advance Nurse Practitioners and Physician Assistants must submit their supervising physician's full name, medical license number, and NPI number. This information is submitted on the online Provider Agreement in TennIIS.

Providers enrolling in the VFC Program agree to all conditions contained in the Provider Agreement and this handbook.

1.2 Initial Enrollment & Annual Enrollment Process

Annual re-enrollment in the VFC Program is required for all providers. Rolling re-enrollment dates ("Phased Enrollment Schedule") are based on the county where a facility is located.

A new facility may enroll at any time. All VFC training and enrollment activities take place within TennIIS; therefore, first-time enrollees not already registered in TennIIS must first register your facility in TennIIS and request a TennIIS user account before requesting a Starter Kit from the VFC Program. Once logged in TennIIS, click on the Document Center link and refer to the Enrollment Walkthrough Guide for detailed instructions on completing the enrollment process.

Initial Enrollment Process (Appendix B):

1. Confirm or establish (1) a **TennIIS** facility registration and (2) an active TennIIS user account.
    - To register a new facility in TennIIS, complete the TennIIS Facility Registration application on the public TennIIS homepage at https://www.tennesseeiis.gov.
    - If the facility is already registered in TennIIS, but the provider does not have a TennIIS user account, contact the TennIIS Registration team at TennIIS.Registration@tn.gov to request one.
2. After step 1, **email** the VFC Enrollment team at VFC.Enrollment@tn.gov with your facility information and your intent to enroll in the VFC Program.

3. **Training** requirements for all new VFC clinics:
    - TennIIS Training – Information is available on the public TennIIS homepage (no log in required) under the TennIIS Training and Education tab. Training is for any staff expected to use TennIIS.
    - Vaccine Ordering Management Training (VOMS) – Link under VFC Training, Training Videos sub-heading. This video shows how to order VFC vaccine and manage your VFC vaccine inventory. Intended for at least 2 people at each location responsible for VFC vaccine ordering (usually the Primary and Back-up VFC Coordinators).
    - CDC Website VFC Training Requirement: the Certifying Provider, Primary and Back-up VFC Contact must complete *two* of CDC's online "*You Call the Shots*" training modules annually: Vaccine Storage and Handling and Vaccines for Children. TIP requires annual submission of certificates of completion as proof. CDC regularly updates these modules. There is a link under the TennIIS training section of the public TennIIS homepage; all *"You Call the Shots"* modules can be reached directly at: https://www.cdc.gov/vaccines/ed/youcalltheshots.html

4. Complete the Routine and Emergency Vaccine Management Plan (**REVMP**).
5. Complete the **online Provider Agreement** in TennIIS.
    - TIP relies on email communications with VFC Program participants. Therefore, all facilities are required to list the following four contacts on the Provider Agreement under "Contact Details" section with appropriate email addresses: *Agreement Signatory* (Certifying Provider), *Primary Vaccine Coordinator*, *Back-up Coordinator*, and a *Facility Contact*.
    - Provider/Practice Profile: TIP uses the numbers of VFC and non-VFC children in the practice to evaluate the appropriateness of VFC vaccine orders and, therefore, they should be reviewed and updated at least annually. A practice that is enrolling in VFC before opening and submits "zero" patient counts must update the practice profile numbers within six months after initial enrollment is approved and may need to update more frequently if the patient base and vaccine demand changes substantially and swiftly.

6. **Submit required documentation:** Scan/Email to VFC.Enrollment@tn.gov or Fax to (615) 401-6831.
    - CDC "*You Call the Shots*" training certificates of completion for the Primary and Back-up Vaccine Coordinators
    - Provider Agreement Signature Page
    - Routine and Emergency Vaccine Management Plan (REVMP)
    - Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit the Notice of Award from the U.S. Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates your designation.
7. The Primary Vaccine Coordinator will receive an email and an alert message in TennIIS during enrollment concerning any change in the status of the online Agreement. Review enrollment comments in the online Agreement located at the top of page one.
8. Once all required enrollment documentation has been approved, the primary contact will receive an acceptance email. Your Regional Immunization Representative (RIR) will then contact you to schedule an enrollment site-visit.
9. After the enrollment site visit and verification of the appropriateness of storage units and temperature monitoring devices (digital data loggers, or DDLs), email five days of temperature readings obtained for each vaccine storage unit from the approved DDLs to the VFC Quality Assurance team at Temperature.Health@tn.gov.
10. After approval following the enrollment visit, place your first VFC vaccine order in TennIIS. As noted above, brand new practices submitting zero patient counts on their Provider/Practice Profile initially will be authorized only to order one box of each vaccine until updated patient population information is submitted within 6 months of opening.

Annual Renewal of Enrollment (Re-enrollment) Process:

Providers must complete re-enrollment within 60 days of the expiration of their current Provider Agreement.

- The Primary Vaccine Coordinator will receive an enrollment reminder email and alert message in TennIIS 60 days before expiration of the current agreement.
- If a Provider Agreement expires without renewal, the facility will be considered to have voluntarily withdrawn from the VFC Program. The provider will not be able to order VFC vaccine and will be contacted by the RIR to collect any remaining VFC vaccine. In order to re-enroll, the facility may have to complete the full initial enrollment process, including a site visit, if enough time has elapsed between enrollments.
    - Practices in the process of completing re-enrollment at the expiration date will not be subject to withdrawal, but may not be able to order more VFC vaccine pending completion.

Steps to complete the re-enrollment process:

1. Annual training requirement: Both Primary and Back-Up Vaccine Coordinators are required to complete annual training:
    - Participate in a VFC Compliance Site Visit or an Educational Site Visit within the last 12 months;
    - Attend VFC Annual Review;
      OR
    - Complete *two* of CDC's online "*You Call the Shots*" training modules: Vaccine Storage and Handling and Vaccines for Children (VFC) for the current enrollment year. Both may be accessed at: https://www.cdc.gov/vaccines/ed/youcalltheshots.html
2. Review, update as needed, and sign pages 8 and 12 of the Routine and Emergency Vaccine Management Plan (REVMP).
3. Login to TennIIS to add and complete a new Provider Agreement for your facility. This feature is located under the Orders/Transfers tab.
4. **Submit required documentation:** Scan/email to VFC.Enrollment@tn.gov or fax to (615) 401-6831.
    - Required Training Records for the Primary and Back-Up Vaccine Coordinators - either certificates of completion for CDC "*You Call the Shots*" training modules or verification of participation in a site visit.
    - Provider Agreement Signature Page

- Routine and Emergency Vaccine Management Plan (REVMP)
- Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) facilities must submit the Notice of Award from the U.S. Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates your designation.

5. The Primary Vaccine Coordinator will receive an email and alert message in TennIIS during enrollment concerning any status changes of the online Agreement. Review enrollment comments in the online Agreement at the top of page one.

VFC Record Retention:

Providers are required to maintain all records related to the VFC Program for a minimum of three years and make these records available upon request for review. VFC records that must be maintained for 3 years include:

- Enrollment documentation
- VFC patient screening and eligibility documentation
- Billing records
- Medical records of immunizations
- Vaccine ordering records
- Vaccine purchase and accountability records (such as VFC Borrowing Forms and invoices proving replacement of borrowed vaccine)

1.3 Provider Identification Number

The VFC Program will issue each facility a unique six-digit Provider Identification Number (PIN). Use this number in **ALL** email, fax, mail and phone interactions with the VFC Program. Referencing the PIN number in the subject line in **ALL** correspondence with TIP will expedite communication.

1.4 Provider/Practice Population Profile

The Provider/Practice Profile is a section within the Provider Agreement in TennIIS. This section of the Agreement defines the number of children who received vaccinations for the full prior year at each facility and identifies patient eligibility status by age group. Providers are required to review and update their patient population numbers annually. If you are completing an annual renewal of enrollment, the Population Profile numbers will auto-populate with administration

data submitted from the prior year. Your billing staff may be able to assist you revising this section of the Provider Agreement if you are using patient records to help determine your Provider Population. It is essential to be accurate when describing your patient population in the Provider/Practice Profile section. TIP uses the information in the profiles to determine the amount of vaccine each provider will need in the year ahead.

Practices are required to maintain private stock vaccine that is sufficient to serve your non-VFC eligible patient population declared on your Provider Population listed in Provide Agreement. The CDC generally considers a "sufficient" supply to be a supply for 4 weeks, based on the size of the program's stated non-VFC patient population.

Special case: Brand New Practice

A new practice that has not yet established a patient base (meaning zeros are put in each patient category) will be restricted to ordering the minimum quantity of each VFC vaccine until a patient profile can be estimated. The practice is **required** to update the Provider Profile with patient numbers within six months of enrollment in the VFC Program; it is likely to be necessary to update more than once if the practice is growing rapidly. This update in the Provider Profile allows the vaccine manager to approve increasing the size of vaccine order amounts as the practice grows.

1.5 Changes in Staff/Facility Status: Notification Required

Providers are required to contact the VFC Program by email or letter (not phone) within **ten days** of any change to the following:

- Agreement Signatory (Certifying Provider that signed Provider Agreement)
- Primary Vaccine Coordinator/Contact
- Back-up Vaccine Coordinator/Contact
- Listed medical providers
- Mailing/shipping address (move locations) notify at least 10 days before
- Vaccine delivery hours
- Facility status (e.g., closure), notify at least 10 days before

Any new Agreement Signatory, Primary or Back-Up Vaccine Coordinator, at a current VFC enrolled facility must complete the two online CDC "*You Call the Shots*" training modules (Vaccines for Children (VFC) *and* Vaccine Storage and Handling) within 30 days of notifying TIP of their new role. If the Primary Vaccine Coordinator is new, an educational visit with your RIR is required within 30 days.

Please Note: Any time a provider moves location, the storage units at the new location must be monitored in place for five days with a VFC-qualified DDL and those 5 days of temperature readings must be submitted to TIP and approved before vaccine is relocated into those units at the new location. For this reason, TIP must be notified *at least* ten business days before moving locations.

1.6 Inactivation and Withdrawal from VFC

Enrolled facilities may be inactivated due to:

Facility Request:	If a facility closes or withdraws from VFC, the practice staff may call TIP, but TIP will require that the decision to withdraw be confirmed in writing, either in a letter of email, *at least* ten business days *beforehand* so VFC vaccine may be retrieved and not wasted.
Failure to comply with VFC requirements:	Failure to comply with VFC Program requirements or to implement appropriate and timely corrective action, may result in inactivation of the provider.
Failure to complete annual re-enrollment:	Current VFC providers whose agreements expire without renewal are inactivated.

Please Note: TIP will contact inactivated providers with instructions on the transfer or return process for all VFC vaccines on hand. The provider is responsible for maintaining proper storage, temperature monitoring, and temperature logs until vaccine is retrieved.

1.7 Fee Policies for Vaccines

Provider receiving federal vaccine must comply with the following fee policies:

1. Immunize VFC-eligible children at no cost to the patient or health plan (i.e., payer) for the cost of a vaccine received through the VFC Program.
2. A provider must not charge a vaccine administration fee to a non-TennCare VFC-eligible child that exceeds the administration fee cap of **$20** per vaccine

dose. For TennCare VFC-eligible children, accept the reimbursement for immunization administration set by the contracted TennCare health plans.

3. A provider must not deny administration of VFC vaccine to an established VFC-eligible patient whose parent/guardian/individual of record is unable to pay the administration fee.
4. Providers may charge an office visit fee in addition to the administration fee.

1.8 Fraud and Abuse

Federal fraud and abuse laws apply to the VFC Program; good stewardship of our federal entitlement program taxpayer dollars is a top priority. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC Program. The following definitions are consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2:

1. Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.
2. Abuse: Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier for the VFC Program to prevent or detect than others. Some examples of potential fraud and abuse that VFC staff might encounter are:

1. Providing VFC vaccine to non-VFC-eligible children
2. Selling or otherwise misdirecting VFC vaccine
3. Billing a patient or third party for VFC-funded vaccine
4. Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a VFC-eligible child

5. Denying VFC-eligible children VFC-funded vaccine because of an inability to pay for the administration fee
6. Failing to implement provider enrollment requirements of the VFC Program
7. Failing to screen for and document eligibility status at every visit
8. Failing to maintain VFC records and comply with other requirements of the VFC Program
9. Failing to fully account for VFC-funded vaccine
10. Negligent failure to properly store and handle VFC vaccine
11. Ordering VFC vaccine in quantities or patterns that exceed the provider's profile or otherwise over-ordering VFC doses of vaccine
12. Negligent waste of VFC vaccine

Any person may contact the Tennessee VFC Program to report any concern or question about possible fraud or mishandling of VFC vaccines. Reports may be anonymous, if desired; all are confidential:

1. To submit a written report, print and complete the VFC Provider Fraud Report form (PH-4130). Submit the completed form (PH-4130) to the Tennessee Immunization Program by fax, e-mail, or mail.
    - Fax: (615) 253-3279
    - E-mail: VFC-Fraud.Health@tn.gov
    - Mail: Tennessee Immunization Program (Attn: VFC Program Manager), 710 James Robertson Parkway, AJT 3rd Floor, Nashville, TN 37243
2. Telephone report: Call the Communicable and Environmental Diseases and Emergency Preparedness (CEDEP) toll free number (800) 404-3006 or (615) 741-7247 and request to speak to the Immunization Program Manager.
3. Report online: Go to the online reporting tool at https://www.tn.gov/health/cedep/immunization-program/ip/vfc/fraud-prevention.html to complete and submit the survey.

Additional resources may also be found on the Federal DHHS Office of the Inspector General (OIG) Exclusions Program webpage.

2. Vaccine Eligibility and Administration Documentation

In order for children to receive vaccines through the VFC Program, eligibility screening and documentation must take place at **each** immunization visit, up to 24 hours prior to vaccination. The only factors considered when screening for VFC eligibility are age and whether the child meets the definition of at least one of the VFC criteria described below.

2.1 VFC Eligibility Categories

Children from birth through 18 years of age (under 19 years) who meet at least one of the following criteria are eligible to receive VFC vaccine:

1. **Medicaid-eligible**: A child who is eligible for the Medicaid program. (For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably and refer to children who have or are eligible for health insurance covered by the TennCare program.)
   Please note: A child is VFC eligible in Tennessee if they have Medicaid in another state but are receiving services in Tennessee.
2. **Uninsured**: A child who has no health insurance coverage. Self-reported status is accepted.
3. **American Indian or Alaska Native (AI/AN)**: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
4. **Underinsured [note limitations of VFC provider options*]**:
   - A child who has health insurance, but the coverage does not include vaccines, or
   - A child whose insurance does not cover all Advisory Committee on Immunization Practices (ACIP) - recommended vaccines. The child would be eligible to receive from VFC only those vaccines not covered by the insurance.
   - A child whose insurance caps its payment for vaccine coverage. The child is eligible to receive VFC vaccine after the insurance cap has been reached. If the cap is expected to be reached as a result of the cost of all of the services provided at the visit, VFC vaccine may be used.

***Please note:** Underinsured children are eligible to receive VFC vaccine only through a FQHC, RHC, or LHD. (Underinsurance, limited coverage, and "caps" are increasingly uncommon coverage options and may only occur in insurance plans not compliant with the Affordable Care Act (ACA). ACA-compliant plans are required to provide all ACIP-recommended immunizations with no deductible or co-pay when administered by an in-network provider).

Health Care Sharing Ministries (Medi-Share): A child with this type of plan should be considered "uninsured" in Tennessee. These plans are nonprofit alternatives to purchasing health insurance and are not recognized as insurance by the Tennessee Department of Commerce and Insurance.

Insurance Coverage: Children whose health insurance covers vaccinations as a benefit **are not eligible** for VFC vaccines. ***This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.***

CoverKids: This state child health insurance plan is not part of Medicaid; children enrolled in CoverKids are ineligible for VFC vaccine.

Insured Exceptions include: (Appendix C)

American Indian/Alaska Native with health insurance that covers immunizations.	AI/AN children are always VFC-eligible. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC Program should be made based on what is most cost beneficial to the child and family.
Insured, plus Medicaid as secondary insurance.	A child may have private health insurance and Medicaid as secondary insurance. This child is VFC-eligible as long as he is enrolled in Medicaid. However, the parent is not *required* to participate in the VFC Program. There are two options: 1. Administer VFC vaccine and bill Medicaid for the administration fee, or 2. Administer private stock vaccine and bill primary insurance for both the cost of vaccine and the administration fee.

2.2 Documentation of Eligibility Screening

As noted earlier, VFC eligibility screening and documentation of eligibility status must take place with each immunization visit, up to 24 hours in advanced. Documentation of the eligibility status of all children under 19 years who are immunized in the practice must be retained and accessible in the health care provider's office for three years. If the eligibility cannot be documented in the EHR, eligibility may be recorded on the Patient Eligibility Screening Record, (Appendix D) and scanned into the EHR or maintained in the paper chart. The record may be completed by the parent, guardian, individual of record, or by the health care provider. Eligibility status documentation (paper or electronic) must include each of the following:

1. Child's first and last name and middle initial
2. Child's date of birth
3. Parent/Guardian/Individual of Record's first and last name and middle initial;
4. Primary provider's name
5. Date of each immunization visit
6. One of the following eligibility statuses:
    - Medicaid eligible/enrolled
    - Uninsured
    - American Indian/Alaska Native
    - Underinsured (served at FQHC, RHC, or LHD)
    - Insured (Private stock vaccine)

2.3 Vaccine Administration Documentation: Medical Record and TennIIS

In accordance with 42 U.S.C. § 300aa–25, all VFC providers must maintain immunization records that include ALL of the following elements:

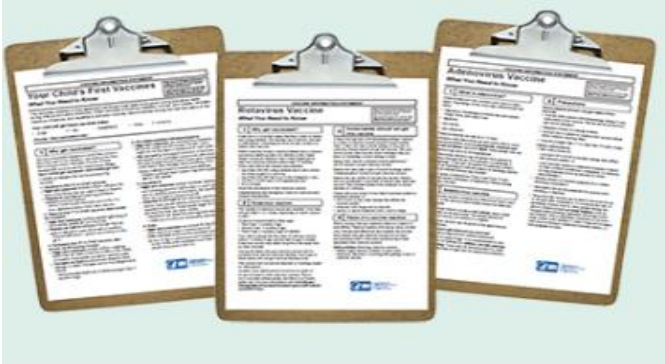
1. Name of vaccine administered
2. Date vaccine was administered
3. Date VIS was given
4. Publication date of VIS
5. Name of vaccine manufacturer
6. Lot number

7. Name and title of person who administer the vaccine
8. Address of clinic where vaccine was administered

VFC providers are **required** to record in TennIIS, every vaccine administered to all patients <19 years of age, regardless of VFC status, within two weeks of administration date.

2.4 Vaccine Information Statement (VIS), Vaccine Adverse Events

The National Vaccine Childhood Injury Act (NCVIA) requires all immunization providers to give the appropriate VIS to the patient (or parent or legal representative). The appropriate VIS must be given **prior** to the vaccination, and must be given prior to **each dose** of a multi-dose series. It must be given **regardless of the age** of the recipient.



Providers must maintain records in accordance with the NCVIA, which includes reporting clinically significant adverse events online or by mail to the Vaccine Adverse Event Reporting System (VAERS) at http://www.vaers.hhs.gov. Deaths or severe reactions possibly associated with immunization also should be reported to TIP by phone.

3. Vaccine Ordering and Accountability

3.1 Ordering Vaccine

All VFC vaccine requests must be placed through the TennIIS Vaccine Ordering and Management System (VOMS). Training materials consisting of short videos and/or PDF instructions on creating, submitting and receiving vaccine orders are available on the TennIIS homepage under the TennIIS Training tab. There is a quick reference guide, Create, Submit and Receive Vaccine Orders, available to assist in the process.

3.2 Vaccine Inventory

VFC providers must offer all ACIP-recommended vaccines for the population they serve and are responsible for proper maintenance of their vaccine inventory. Provider sites must reconcile their VFC vaccine inventory every 30 days using VOMS. Reconciliation is required by CDC and is an accounting of vaccine doses administered, wasted, expired, lost (unaccounted for) and the vaccine doses currently in your inventory.

1. Providers are required to have two separate vaccine inventories: one for publicly purchased vaccines and one for privately purchased vaccines.
2. Providers are required to reconcile their inventory every 30 days; **even if a vaccine order is not placed.**
3. Vaccine requests cannot be processed unless reconciliation reports are up-to-date in TennIIS.
4. Review the TennIIS Quick Reference Guide Inventory Reconciliation.
5. VOMS is only for federal vaccine. Private stock should never be manually entered into VOMS.

3.3 Receiving VFC Vaccine

Providers must have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity. All staff must be trained to recognize a vaccine shipment and the procedures to follow once received. The following steps should happen upon receipt of a vaccine shipment:

1. Open vaccine packages immediately
2. Inspect the vaccine and packaging for damage

3. Compare the vaccine received with the vaccine products that appear on the packing list
4. Immediately store at appropriate temperatures
5. Check the temperature monitor readings (if available)
6. (Frozen vaccine only) Verify length of time the vaccine was in transit. Check the shipper insert supplied in the box. This insert will let you know the acceptable transit time based on the shipment date on their packing list.
7. If the vaccine shipment is compromised, the order is wrong (not the vaccine or the quantity ordered), or there is a problem with the temperature monitors, **contact the TIP VFC Program immediately, within 2 hours**, at (615) 532-8509 or (800) 404-3006. It is critical that TIP contact McKesson the same day the vaccine arrived at your site, otherwise the shipper may not be held accountable for replacing a damaged or improper shipment.
8. **Login to TennIIS/VOMS and electronically indicate receipt of the order in the Orders/Transfer page**.

3.4 VFC Vaccine Returns

Report all VFC vaccine that has expired or has been spoiled/wasted electronically in TennIIS/VOMS so it can be returned to McKesson. The return process must be completed in VOMS in order to receive a shipping label to send vaccine back to McKesson. Expired vaccine needs to be returned within 60 days. See the quick reference guide for Returning Vaccines available on the TennIIS homepage.

Influenza vaccine ordering (pre-booking) and return procedures are managed separately outside VOMS: follow specific instructions provided by the Vaccine Manager for return of expired influenza vaccine each year.

3.5 Borrowing of Vaccine

VFC-enrolled providers are expected to maintain adequate inventories of vaccine, at least four weeks of inventory, to administer to their privately insured and VFC-eligible children. Borrowing of vaccine between VFC and private vaccine inventories is not allowed unless specifically authorized in advance by the TIP VFC Program under extraordinary circumstances. For situations where borrowing is needed and approval is sought, contact the TIP VFC Program at (615) 532-8509 or (800)404-3006.

If approved, borrowing must be documented "dose-by-dose" for each patient on the Vaccine Borrowing Form (Appendix E). Any doses borrowed from VFC inventory must be replaced within 30 days. Replacement must be documented on the borrowing form and submitted to TIP.

Please note: At the beginning of each influenza vaccine season there are differences in the arrival times of influenza vaccines for VFC and non-VFC patients. Borrowing between inventories of influenza vaccines is not authorized unless the VFC Program notifies providers of a change due to an extraordinary problem.

3.6 Vaccine Transfers

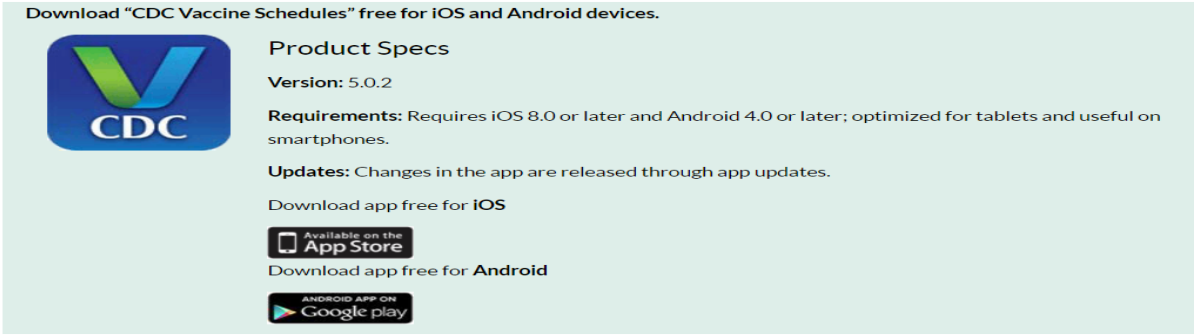
It is important to report to TIP any VFC vaccine with short expiration dates (vaccines expiring within three months) unlikely to be used before they expire. This allows the VFC Program the opportunity to have vaccines transferred to another VFC site. Contact your RIR to determine if there are other VFC providers in your area that could use the expiring vaccine.

3.7 Vaccine Schedules

VFC providers are required to comply with the immunization schedules, dosages, and contraindications recommended by the ACIP, unless:

1. In the provider's medical judgment, and in accordance with accepted medical practice, such compliance is medically inappropriate for the child.
2. State law, including laws pertaining to religious and other exemptions, applies.

Immunization schedules are available on the CDC website at: https://www.cdc.gov/vaccines/index.html. You may download the CDC Vaccine Schedule app on your iOS and Android devices.



4. Vaccine Storage and Handling

4.1 Storage and Handling

Just 10 doses of each routinely recommended child/adolescent vaccine is valued at over $10,000; most practices have far larger inventories. Vaccines must be stored appropriately in order to work as designed. The temperature controlled environment used to maintain and transport vaccines in optimal condition is called the vaccine cold chain. An effective cold chain relies on three main elements:

1. Effectively trained personnel
2. Reliable storage and temperature monitoring equipment
3. Accurate vaccine inventory management

Vaccine storage and handling practices are only as effective and successful as the staff that implements them. A well-trained staff, familiar with key storage and handling principles, is critical to safeguarding your vaccine supply and the safety of your patients.

4.2 Vaccine Coordinator (aka Primary VFC Contact)

The primary VFC Contact at a site is responsible for ensuring all vaccines are stored and handled correctly. Each site is also required to designate a second staff member to serve as back-up in the absence of the primary VFC contact. The certifying provider on the Provider Agreement is not normally the Primary or Back-up VFC Contact because the provider normally does not carry out VFC Contact responsibilities. The certifying provider may be the VFC Contact in circumstances where there is no more appropriate alternative and where they comply with all VFC Contact responsibilities. For organizations that have multiple sites, a VFC Contact may not be assigned to more than one site; **the assigned primary and back-up VFC Contact must be predominantly on-site at their designated location**. Both VFC Contacts should be fully trained in routine and emergency policies and procedures.

VFC Contact responsibilities include:

1. Ordering vaccines
2. Overseeing proper receipt and storage of vaccine deliveries
3. Documenting vaccine inventory information

4. Organizing vaccines within storage units
5. Setting up temperature monitoring devices
6. Reading and recording storage unit temperatures a minimum of 2 times (morning and afternoon) each workday
7. Reading and recording minimum/maximum temperatures from a digital data logger at start of each workday, preferably each morning
8. Reviewing and analyzing temperature data at least weekly to detect any concerning temperature trends
9. Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
10. Removing expired vaccine from storage units
11. Responding to out-of-range temperatures (temperature excursion, "TE")
12. Maintaining all documentation, such as inventory and temperature logs
13. Ensuring staff is properly trained
14. Monitoring operation of storage equipment and systems
15. Overseeing proper vaccine transport (if necessary)
16. Overseeing emergency preparations
17. Primary VFC Contact is responsible for providing training for their back-up

4.3 Vaccine Storage Units

Refrigerators and freezers typically used for vaccine storage are available in different grades (household and purpose-built), size, and types (stand-alone and combination refrigerator/freezer). Purpose-built units are sometimes referred to as "pharmaceutical grade" and are designed specifically for storage of biologics. It is important that the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season) without crowding. The following storage units are acceptable for storing VFC vaccine:

1. A purpose-built unit for vaccine storage designed to either refrigerate or freeze (can be compact, under-the counter-style or large units).
2. A stand-alone frost-free refrigerator, meaning a self-contained unit that only refrigerates.*
3. Providers are encouraged to use a stand-alone automatic defrost freezer. If a provider decides to use a stand-alone manual defrost freezer, they will need

a back-up freezer that is approved to store vaccine, for use when defrosting their main freezer unit.

- Document defrost plan in the Routine and Emergency Vaccine Storage Plan
- The unit requires defrosting, when defrost has accumulated to a thickness of approximately 1 cm
- Guidance on defrosting a manual freezer is available here

TIP approval is strongly recommended prior to purchasing a new vaccine storage unit to ensure it meets the VFC Program requirements. Any time a provider purchases a new vaccine storage unit, it is **required** that five days of temperature readings from a VFC-compliant DDL are reviewed and approved by TIP **prior to vaccine being placed in the unit(s).** This prevents practices from purchasing the wrong kind of storage unit or using a unit that is not functioning properly after installation.

In addition to combination refrigerator/freezer units, dormitory or bar-style refrigerators are not permitted for **ANY** vaccine storage. A dormitory or bar-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the "freezer" within the refrigerator. Such refrigerators place vaccine at a high risk of freezing.

It is important to protect the power source for all vaccine storage units with clear warning labels on both the plug and circuit breaker for each storage unit. Avoid using power outlets that can be tripped or switched off including:

1. Built-in circuit switches (may have reset buttons)
2. Outlets that can be activated by a wall switch
3. Multi-outlet power strips
4. Electrical cords

4.4 Temperature Monitoring Devices

VFC providers are required to use a DDL with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing VFC vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and mass vaccination clinics.

There may be providers who have purpose-built or pharmaceutical-grade equipment (e.g., doorless or dispensing units) with temperature monitoring capabilities that may be as reliable as a DDL in monitoring vaccine temperature. Contact TIP to determine if your unit is capable of meeting VFC temperature monitoring device requirements. **The DDL should include the following features:**

1. A detachable, buffered probe (or digitally buffered device that mimics a buffered probe)
2. Alarm (audible or visual) for out-of-range temperatures – alarm parameters should be set as follows:
    - Refrigerator low alarm (too cold) set to trigger after 15 consecutive minutes or longer below 2.0°Celsius
    - Refrigerator high alarm (too warm) set to trigger after 60 consecutive minutes above 8.0°Celsius
    - Freezer high alarm (too warm) set to trigger after 60 consecutive minutes above -15°Celsius
3. Current, minimum, and maximum temperatures
4. An active display outside the unit so there is no need to open the unit door while conducting routine checks of the storage temperatures
5. Low battery indicator
6. Accuracy of +/-0.5°C
7. Memory storage of at least 4,000 readings
8. User programmable logging interval (or reading rate) – **recommend set interval for every 15 minutes**
9. Data is easily downloadable for review
10. DDLs are required to record in Celsius to fully account for the acceptable vaccine storage temperature range. Due to rounding of numbers when converting from °C to °F, the FDA-licensed acceptable temperature range for vaccine storage is smaller if using °F measurements, so temperature excursions are more likely on °F devices.

In addition, VFC providers **must have at least one back-up DDL** with a valid and current certificate of calibration on-site to ensure that temperature assessment and recordings can be performed twice a day. A back-up DDL must be readily available in case a DDL in use is no longer working or calibration testing of the current DDL is

required. CDC recommends that the back-up DDL be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion. The back-up DDL should have a different calibration retesting date than the primary so one may be used while the other is being replaced or sent out for re-calibration.

4.5 Certificate of Calibration Testing

Valid and current Certificates of Calibration Testing (or Reports of Calibration Testing) must be maintained on all DDLs used in vaccine storage units. Calibration testing and traceability must be performed by:

1. A laboratory accredited by an ILAC MRA signatory body (recommended by CDC). Certificate must include the following elements:
    - ILAC/MRA signatory body-accredited laboratory
        a. Laboratory accreditation should be clearly identifiable (to search ILAC-accredited laboratories, see box below)
        b. An ILAC MRA-accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards
        c. The certificate may have an Accrediting Body Symbol, which is the logo, and a unique laboratory code or certificate number included on the certificate
    - Name of Device (optional)
    - Model Number
    - Serial Number
    - Date of Calibration Testing (report or issue date)
    - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 0.5°C.
2. An entity that provides documentation demonstrating the calibration testing performed meets ISO/ IEC 17025 international standards for calibration testing and traceability. Certificate must include the following elements:
    - Name of Device (optional)
    - Model Number
    - Serial Number

- Date of Calibration Testing (report or issue date)
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 0.5°C
- Statement that calibration testing conforms to ISO 17025

If you are uncertain if the certificate you have conforms to these requirements, contact TIP or your RIR for help.

4.6 Temperature Probe Placement

The probe of your DDL should be placed in the central/middle area of the storage unit *with* the vaccines. Do not place the temperature probe in the doors, near or against the walls, close to vents, or on the floor of the vaccine storage unit because temperatures in these locations can differ significantly from the temperature in the zone where vaccine is actually stored.

4.7 Temperature Monitoring

Temperature monitoring is the primary responsibility of the Primary VFC Contact and/or Back-up Contact. It is required that temperatures are reviewed within each vaccine storage unit **twice a day** (morning and afternoon) and the **minimum and maximum temperatures for the past 24 hours are reviewed each morning**. These temperature readings must be documented daily, as should any actions that are taken if the temperatures readings are out of acceptable range.

If a DDL has the ability to record twice a day readings (e.g., Fridge Tag and Log Tag), the provider should use this function and document daily readings on the Vaccine Storage Unit Digital Data Logger Sign-off Sheet so that the identity of the person checking logs is recorded. If the DDL report is able to document the initials of the person completing the twice a day readings, the sign-off sheet does not need to be completed. If the DDL does not have the ability to document the twice a day readings on the DDL report, provider should document daily readings on the TIP Temperature Logs for Refrigerators and Freezers. **VFC requirement:** DDL reports must be printed, reviewed and signed by the Primary or Back-up VFC Contact each week and maintained with temperature logs for three years.

The refrigerator should maintain temperatures between 2°Celsius and 8°Celsius at all times. The average daily temperature target is +5°Celsius. The freezer should

maintain temperatures between minus (-) 50°Celsius and minus (-) 15°Celsius; suggested target is minus (-) 20°Celsius or colder. Most freezers can safely be set on their coldest setting because they do not reach -50°C unless designed to do so.

Stand-alone refrigerator

Stand-alone freezer

4.8 What is a Temperature Excursion (TE)?

A TE occurs any time the temperature in a refrigerator unit is outside 2°C through 8°C or the temperature in a freezer unit is above -15°C. TIP must be notified as quickly as possible during business hours or on the next business morning (Monday – Friday 8:00am – 4:30pm Central Time) and before any vaccine is administered, if any one of the below criteria are met:

1. Refrigerator temperature dipped below 2°C for 15 consecutive minutes (or longer).
    a. Freezing temperatures below 0°C quickly damages vaccine. Quick action may save vaccine if temperature begins to get too cold.
2. Refrigerator above 8°C for at least 60 consecutive minutes.
3. Freezer above -15°C for *more* than 60 minutes.
    b. Frost-free freezer defrost cycles may go above -15°C for short periods. Vaccine stability data supports these types of excursions.
4. TE is part of a pattern of frequent excursions, regardless of duration.
5. You are concerned about TE even though it doesn't meet above criteria.

Please Note: Review the Temperature Monitoring and Excursion Guide on our website for more details on vaccine storage units and temperature monitoring.

4.9 Reporting a Temperature Excursion

Report TE by calling the TIP QA Team at (800) 404-3006 as soon as possible during business hours (Monday – Friday 8:00 am – 4:30 pm Central Time). If the call is not answered, call the CEDEP main desk at (615) 741-7247 and ask them to locate someone in TIP.

1. If TE is still occurring (temperatures are currently out of range) take the following steps to restore proper storage conditions:
    - Attempt to return vaccine to proper storage conditions:
        a. Check to see if the storage unit is unplugged
        b. Check to see if the storage unit door is open and is sealed adequately
        c. Check the thermostat setting
        d. Check location of the DDL probe; should be in the middle of the unit with the vaccine and properly attached to the DDL
        e. Check coils and vents for excess dust
    - Quarantine vaccine; label "Do Not Use until Notified by TIP"
        a. Do not use any vaccine until approved by TIP
    - Immediately call the TIP QA team (if during business hours)
    - If instructed by TIP, or if after hours, follow your Emergency Vaccine Storage and Handling Plan posted on or beside the storage unit. If storage unit is not back in-range, transfer vaccine to the designated back-up location.
    - Download temperature log from digital data logger or document current temperature reading on temperature log
    - Note how long the temperature was out of range
    - Note the minimum/ maximum temperatures
    - Fax data logger report or temperature log to (615) 401-6829 or email to Temperature.Health@tn.gov **(include the VFC PIN and name of contact)**
2. If temperature is currently "in-range" complete the following steps:
    - Troubleshoot – can you identify why it went out of range?
    - Quarantine vaccine; label "Do Not Use until Notified by TIP"
    - **Do not use any vaccine until approved by TIP**
    - Immediately call the TIP QA team, if during business hours

- Download temperature log from digital data logger or document current temperature reading on temperature log
- Note how long the temperature was out of range
- Note the maximum and minimum temperatures
- Fax data logger report or temperature log to (615) 401-6829 or email to Temperature.Health@tn.gov

3. Responding to TE **After TIP Business Hours:**
    - Attempt to return vaccine to proper storage conditions:
        a. Check to see if the storage unit is unplugged
        b. Check to see if the storage unit door is open and is sealed adequately
        c. Check the thermostat setting
        d. Check location of the probe; should be in the middle of the unit with the vaccine
        e. Check the coils and vents for excess dust
    - Quarantine vaccine; label "Do Not Use until Notified by TIP"
    - Do not use any vaccine until approved by TIP
    - Follow the Emergency Vaccine Storage and Handling Plan posted on or near the unit.
        a. If unit is not currently in-range and vaccine cannot be reliably and promptly returned to proper temperatures, transfer vaccine to the designated back-up location listed in your Emergency Vaccine Storage and Handling Plan.
        b. You may also use the emergency vaccine transport qualified pack-out (Appendix F) published by the CDC for temporary storage up to 8 hours. For packing instructions, see http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf
    - **If experiencing a power outage**, contact utility company. **If restoration is expected within four hours, do not move vaccine**. Keep the door closed and monitor temperature. This brief TE may be less harmful that transporting vaccine. If power outage is going to last more than four hours, follow your Emergency Vaccine Storage and Handling Plan.
    - ***As soon as TIP offices open*** (8AM Central Time), the next business day contact the QA Team to report TE.

- If guidance is needed because vaccines need to be used *before* the next business day do one of the following (you will still need to call TIP the next business morning):
    a. Contact vaccine manufacturer's customer service lines directly to report the problem and obtain vaccine use guidance.
    b. Alternatively, you may call (615)741-7247 and listen to the message to obtain the phone number of the on-call senior epidemiologist for CEDEP. This person will provide a basic consultation but will *not* provide advice on the viability of the vaccine. They may instruct you to contact the manufacturer for guidance on vaccine usability if vaccine must be administered before TIP offices are open.

4. If the TE is not reported promptly during business hours, or within the next business day if after hours, and there is vaccine loss as a result of the TE, the following actions will be taken:
    - Provider will be in probationary status for 6 months with additional education and supervision of storage conditions.
    - Provider will need to submit weekly temperature logs to their RIR for four weeks and then monthly for the next five months.
    - RIR will conduct an on-site education visit for the certifying provider, Primary and Back-up VFC Contact.
    - Provider may be required to service or purchase a new unit within six weeks; vaccine orders will be placed on hold. The invoice and five days of temperatures will need to be sent to TIP before approval is given to store VFC vaccine in unit.
    - Provider will receive at least one unannounced storage and handling visit during the six month period.
    - At the successful conclusion of the six month probation the provider will resume routine monitoring.
        a. If unable to maintain compliance with VFC vaccine storage and handling requirements during this period the site will be suspended from the VFC Program for six months. The RIR will pick up VFC vaccine. TIP will notify TennCare.

5. If TE is not reported promptly during business hours, or promptly the next business day (if found after hours), and there is **no** vaccine loss the following actions will be taken:
    - Provider will be placed on six month probation.
    - Provider will need to submit weekly temperature logs to the RIR for four weeks and then monthly for the next five months.
    - RIR will conduct an on-site education visit for the certifying provider, Primary and Back-up VFC Contact.
    - At the successful conclusion of the six month probation the provider will resume routine monitoring.
        a. If unable to maintain compliance with vaccine storage and handling requirements during this period, the site will be suspended from the VFC Program for six months. The RIR will pick up VFC vaccine. TIP will notify TennCare. Re-enrollment will be contingent on the ability to sustain compliance in order to avoid costly vaccine waste.

Can you spot the difference?

Properly stored vaccine
Full Potency

Improperly stored vaccine
Diminished potency

Vaccine appearance is NOT a reliable indicator that vaccines have been stored in appropriate conditions.

5. Vaccine Management

5.1 Routine Vaccine Storage and Handling Plan

VFC providers are required to develop, maintain and implement a routine vaccine storage and handling plan. The plan must be updated annually and include a review date and the signature of the individual responsible for the content. The minimum required components of the plan include the following:

1. Name of the current primary VFC Contact and at least one back-up
2. General operations for proper vaccine storage and handling practices: Temperature monitoring
    - Vaccine storage (e.g., equipment, placement)
    - Vaccine shipment receiving procedures
3. Vaccine ordering procedures
4. Inventory control (e.g., stock rotation)
5. Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
6. Documentation of staff training on all plan elements
7. Recorded review date within the last 12 months
8. Signature of the individual responsible for the content

5.2 Emergency Vaccine Storage and Handling Plan

VFC providers are required to have an emergency vaccine storage and handling plan. The plan must include guidance on what to do in the event of:

1. Refrigerator or freezer malfunctions
2. Power failure to vaccine storage units
3. Natural disasters or other emergencies that might compromise vaccine storage conditions

The plan must include policies and protocols for maintaining the vaccine cold chain during transport to and while stored in emergency storage locations. We recommend your plans include the use of a commercial vaccine transport box qualified to maintain around 5ºC for a specified number of hours or the use of the CDC emergency transport vaccine qualified pack-out (Appendix G), http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-

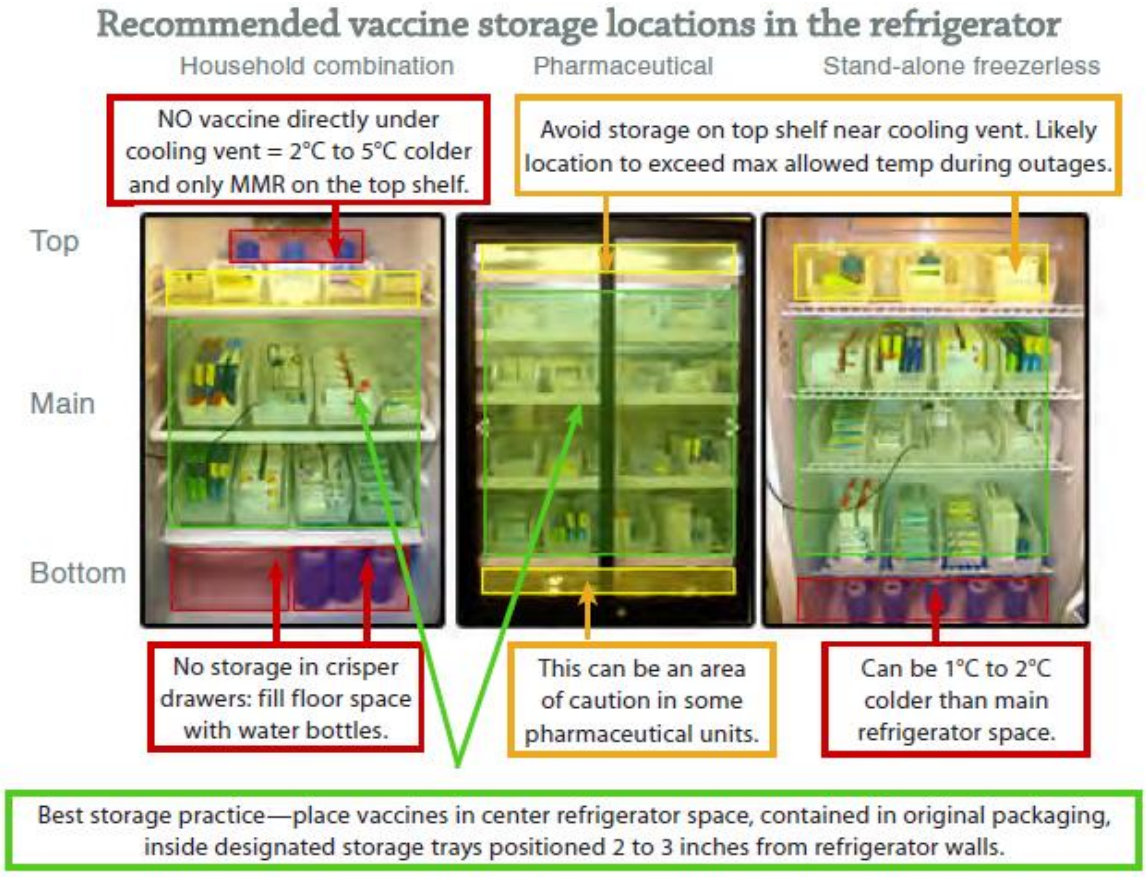
transport.pdf. A DDL is required to remain with the vaccine at all times, including transport. The vaccine storage units and DDLs used at the emergency location site must be in compliance with VFC requirements. A Routine and Emergency Vaccine Management Plan template is at: https://www.tn.gov/content/dam/tn/health/documents/immunizationrequirements/REVMP.pdf

5.3 Vaccine Storage

Placement and organization within the storage unit is vital to maintaining vaccine stability. The following are best practices for day-to-day vaccine management:

1. Store vaccines in their original packaging (including UV protective bags used by CDC's centralized distributor for repackaged vaccines only).
2. Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
3. Do not store vaccines in the doors, vegetable bins, or floor of the unit, or under or near cooling vents.
4. Do not store food or drink in vaccine storage units.
5. Place water bottles throughout refrigerator and freezer storage units and frozen coolant packs in order to:
    - Stabilize or extend temperatures during a power outage,
    - Dampen the effects of frequent opening/closing of door, and
    - Serve as physical barriers preventing the placement of vaccines in areas of the unit that are at higher risk for TEs.
6. Rotate vaccine every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front. Immediately remove any expired vaccine from storage units. Bag and label all expired vaccine: "DO NOT USE".
7. Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. For multi-dose vials only, indicate on the label the date and time it was reconstituted or first opened.
8. Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
9. Limit access to the vaccine supply to authorized personnel only.

10. Install locks on refrigerators and, if possible, the electrical plug. Label the plugs “Do Not Disconnect.”
11. Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
12. In larger clinics, we recommend a source of back-up power (generator) and a security system to alert personnel in the event of a power outage.
13. If applicable, test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).
14. In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC and TIP strongly recommend NOT pre-drawing doses before they are needed.
    - Manufacturer pre-filled syringes are a good option in mass vaccination clinics. Although <u>not</u> recommended, during mass vaccination clinics a provider may pre-draw up to 10 doses from a multi-dose vial and administer them (if administered by the person who drew them up).



6. Quality Assurance Visits

Federal and state requirements mandate that TIP conduct Quality Assurance (QA) visits, assessments and education with each enrolled VFC provider.

6.1 Provider Enrollment Visit

This visit is required for new enrolling providers or former VFC providers that have had a break between enrollments. The purpose of this visit is to provide education on VFC Program requirements and verify the facility has the appropriate resources to implement program requirements.

6.2 VFC Compliance Site-Visit

A compliance site visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state VFC requirements. It involves administration of a questionnaire, evaluating compliance with requirements and providing education. During the visit, there will be a formal review of vaccine management practices as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring.

6.3 Unannounced Storage and Handling Site-Visit

The VFC Program requires unannounced storage and handling site visits be conducted to serve as "spot checks" on facility vaccine management practices.

Please Note: The RIR will meet with the provider and staff after any VFC compliance or unannounced storage and handling visit is completed to review findings. Education will be provided for any issues identified and a corrective action plan will be completed.

6.4 Annual Education Requirement

The primary and back-up VFC contacts are required to complete an annual educational session. The requirement can be met by participating in a VFC Compliance Site Visit (both the Primary and Back-up VFC Contact must attend), attending the VFC Annual Review, or by completing the CDC's online You Call the Shots modules "Vaccines for Children (VFC)" and "Vaccine Storage and Handling".

6.5 VFC Contact

Any in-person, phone or written contact with a provider (not related to the most recent VFC compliance or unannounced storage and handling visit). "VFC contacts" are directly related to communicating VFC Program requirements. Clarifying vaccine orders, formal educational opportunities (to meet the annual training requirement), and follow-up for VFC compliance or unannounced storage and handling visits are not classified as VFC contacts.

A provider can request additional education and training: contact your RIR.

6.6 Assessment, Feedback, Incentives, eXchange (AFIX) Visit

AFIX (Assessment, Feedback, Incentives, and eXchange) is a research-supported continuous quality improvement and collaborative learning process designed by CDC to support VFC providers to increase vaccination of children and adolescents with all ACIP-recommended vaccines. This is achieved by reducing missed opportunities to vaccinate and improving immunization delivery practices at the provider level. Doing so will ultimately reduce the number of vaccine-preventable diseases in the patient population.

AFIX visits are conducted by RIRs with VFC providers in conjunction with VFC Compliance Visits. The goals of these visits ensure providers are:

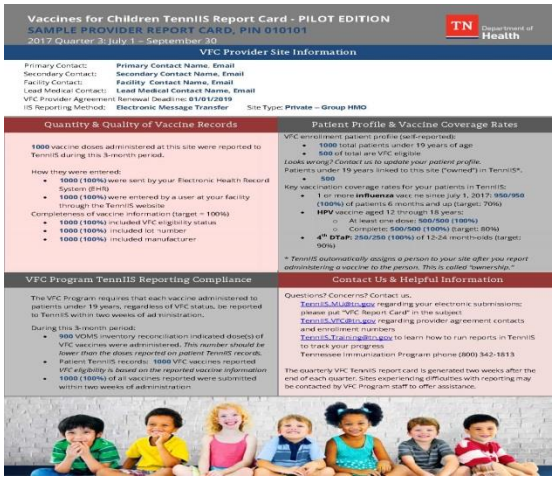
- aware of and knowledgeable about their immunization rates and missed opportunities to vaccinate
- motivated to incorporate changes into their current practices
- ready to try new immunization service strategies
- capable of sustaining improvements to their vaccination delivery services

The AFIX process begins with assessments conducted on 24-35 month old children and 13-17 year old adolescents, using immunization data on a provider's active patients in TennIIS. The results of the coverage assessments are shared with the provider and staff during the AFIX site visit. The RIR and the provider will work together to develop strategies to improve immunization services and raise coverage rates for children and adolescents. Within 3-6 months after the initial assessment date, the RIR will conduct a follow-up visit to review new coverage rate reports and discuss the success of QI strategies selected during the feedback visit.

Only immunizations recorded in TennIIS are assessed during the AFIX process. **For an accurate AFIX assessment, practices should add missing historical doses when updating a patient's record with an administered dose and remove inactive patients from their facility.** Practices with electronic connections to TennIIS may upload these history shots from their EHR in a one-time process by contacting the TennIIS team at TennIIS.MU@tn.gov with a subject line of "VFC Backloading" for details.

6.7 Vaccines for Children TennIIS Report Card

The primary purpose of this quarterly report card is to improve the quality of immunization services provided to VFC and non-VFC children in Tennessee. This focused, quarterly data quality report will help your practice and TIP work together to improve the quality of TennIIS records for your patients. It will also track your progress in compliance with the VFC requirement to report all doses administered to patients <19 years regardless of VFC status within two weeks of administration. Those who are found to not be administering shots in TennIIS will be contacted by Central Office staff to submit a Corrective Action Plan. If other significant problems are noted, your RIR will reach out to help you resolve any barriers. With reliable, comprehensive immunization records available to all healthcare providers throughout your patients' lives, TennIIS can achieve its potential to simplify, expedite and improve immunization services, including coverage rates and compliance with childcare, school and college immunization requirements.



7. Mobile Immunization Clinic

Under conditions outlined below, VFC providers may incorporate a mobile immunization clinic into their practice. A mobile immunization clinic allows providers to vaccinate children at non-traditional locations (e.g., schools and health fairs) while maintaining a clinic setting without a break in the vaccine cold chain.

The mobile immunization clinic is an extension of the provider's practice and will use the same unique VFC provider identification number (PIN) already assigned to the provider. The mobile immunization clinic must comply with all VFC Program requirements listed in the Provide Agreement. In addition to adhering to all general VFC Program requirements, the following conditions must be met:

1. The provider must be enrolled in the VFC Program in good standing.
2. The VFC provider must have protocols in place to ensure that the outreach efforts meet all VFC requirements, including how the provider is establishing vaccine needs (provider profile) and overseeing vaccine ordering for each clinic site to ensure that proper amounts of VFC stock are transported on each clinic day.
3. The mobile immunization clinic must pass the storage and handling site-visit; this is an *initial* and *annual* requirement.
    - Any staff participating in the mobile immunization clinics must receive VFC training either by the primary or back-up VFC Coordinator.
    - Any staff participating in the mobile immunization clinics must complete the same annual VFC training required of the primary and back-up VFC contacts.
4. Vaccines are required to be shipped to the provider's primary clinic site listed in the Provider Agreement. Vaccines should only be transferred to the mobile unit on the day of the clinic.
5. Mobile Immunization Clinics can only be conducted within the state of Tennessee; VFC-eligible children are not required to be TN residents.
6. The provider must complete the Mobile Immunization Clinic Log (Appendix H) that lists the clinic dates, locations and the vaccine amounts by fund type, VFC and private stock, that will transported for each clinic.
7. Vaccine storage and handling equipment must meet CDC requirements:
    - A stand-alone refrigerator

- A separate stand-alone freezer
- VFC-compliant DDL for temperature monitoring in each storage unit
- Prior to transferring the vaccine to the mobile immunization clinic the storage units must be operational and temperatures in-range (refrigerator temperature steady between 2°C – 8°C, hovering around 5°C; freezer temperature consistently colder than minus (-)15°C).
- DDLs that are routinely stored outside a refrigerator or freezer should be placed in functioning storage unit at least 6 hours, or the night before, to allow time for them to acclimate and register any issue.
- The vaccine should be transferred to the mobile immunization clinic inside a cooler; transfer should not take longer than 15 minutes. If the transfer will take longer than 15 minutes, use the "Packing Vaccines for Transport during Emergencies" guidance or a commercial transport box qualified to maintain proper temperatures during transfer.

8. Only staff that has completed VFC training may transfer vaccines between provider practice and the mobile unit.
9. Only amounts of VFC vaccines that are appropriate, based on VFC need, should be transported to each scheduled clinic.
10. Upon arrival at the clinic site, the mobile clinic staff must ensure that vaccine is stored to maintain appropriate temperature throughout the clinic day:
    - Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic, using a DDL.
    - Temperatures during transport (if >15 minutes) and mobile immunization clinic hours must be documented hourly on the Hourly Vaccine Temperature Log (Appendix I).
11. At the end of each clinic day, the mobile immunization clinic staff must:
    - Print the temperature data logger report at the end of the clinic day and attach to the mobile clinic temperature log. The primary or back-up VFC Coordinator needs to review temperature logs and sign the Hourly Vaccine Temperate Log prior to the vaccine being returned to the primary clinic's storage units.
    - Vaccines exposed to TEs must be labeled "Do Not Use", placed in storage unit(s) at proper temperatures, and TIP needs to be contacted

in accordance with TE procedures described elsewhere in this guide. The vaccines should not be used until TIP has verified they are usable.
- Temperature logs from the mobile immunization clinic must be stored with the primary clinic logs and kept on file for 3 years. During a VFC Compliance Site-Visit temperature logs will be reviewed.

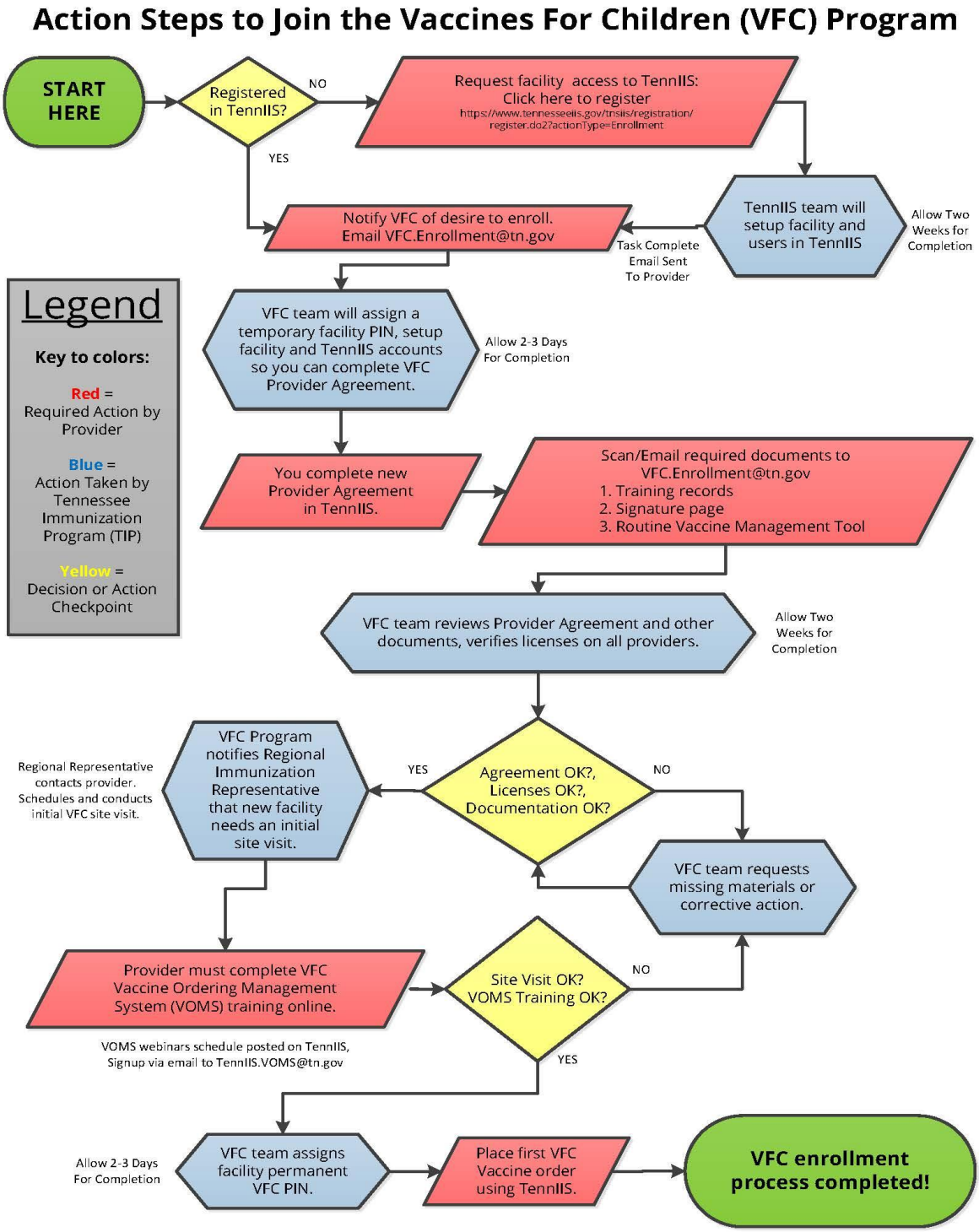
12. VFC eligibility must be screened and status documented at the time of service.
    - If the eligibility cannot be documented in the EHR, eligibility may be recorded on the Patient Eligibility Screening Record, and scanned into the EHR or maintained in the paper chart.
    - All eligibility information must be maintained for **three** years per VFC requirements for maintaining documents.
    - If working with a school, the school should send permission slips/Eligibility Screening Form home with the student prior to the scheduled clinic date, and have it available on the date of service. It is not acceptable to presume all students are VFC-eligible because no eligibility screening was conducted.
13. All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42 US Code 300aa-25):
    - Name of vaccine
    - Date vaccine given
    - Name of vaccine manufacturer
    - Vaccine lot number
    - Signature & title of person administering vaccine
    - Address of clinic where given
    - Publication date of VIS
    - Date VIS given to parent/guardian
14. All immunizations must be entered in TennIIS within two weeks of administration.
15. Quality Assurance Visits will be conducted annually for the mobile clinic.

- The mobile immunization clinic will be included in the primary clinic's VFC compliance site visit. If a compliance visit is not scheduled during the upcoming year, a storage and handling visit will be performed.
- Failure to meet the VFC requirements for eligibility, documentation and storage and handling may result in withdrawal of VFC approval for use of the mobile clinic for VFC vaccines.

Appendix A: Resources

Resource	Information about Resource
CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook	Includes principles of vaccination, immunization general recommendations and strategies, and information regarding vaccine safety, storage and handling, and details regarding administration of individual vaccines. **Website:** http://www.cdc.gov/vaccines/pubs/pinkbook/index.html
CDC: Vaccines and Immunizations	Provides information on immunization schedules, publications about vaccine-preventable diseases, and much more. **Website:** http://www.cdc.gov/vaccines **Phone:** 1-800-CDC-SHOT (1-800-232-4636)
CDC: Vaccine Information Statements (VIS) and Email VIS Update Service	Current VIS; sign up to receive update notices via email. **Website:** http://www.cdc.gov/vaccines/hcp/vis/index.html
CDC: Vaccine Storage & Handling Toolkit	Information regarding best practices for vaccine storage and handling. **Website:** http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Immunization Action Coalition (IAC)	Evidence-based vaccine information, VIS in multiple languages, "Ask the Experts", free print materials, information on vaccine-preventable diseases, and much more. **Website:** http://www.immunize.org
CDC You Call the Shots Training	Vaccine Storage and Handling (module 10) Vaccines for Children Program (module 16) **Website**: https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp

Appendix B: Flowchart for Initial VFC Enrollment



Appendix C: Examples of Insured Exceptions

INSURED EXCEPTIONS

AI/AN with Health Insurance that Covers Immunizations:

AI/AN children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC program should be made based on what is most cost beneficial to the child and family.

Insured and Medicaid as Secondary Insurance:

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC program. There are options for the parent and provider. These options are described below:

Option 1

A provider can administer VFC vaccine to these children and bill the Medicaid agency for the administration fee.

In most healthcare situations, Medicaid is considered the "payer of last resort." This means that claims must be filed to and rejected by all other insurers before the Medicaid agency will consider payment for the service. This is not true of the VFC vaccine administration fee for Medicaid-eligible children.

The Medicaid program must pay the VFC administration fee because immunizations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once the claim is submitted to Medicaid, the state Medicaid agency does have the option to seek reimbursement for the administration fee from the primary insurer.

Please note: If the state Medicaid agency rejects a claim for a vaccine administration fee for a child with Medicaid as secondary insurance, stating the claim must first be submitted to the primary insurer for payment, the provider should notify the awardee. The awardee should notify their CDC project officer so that CDC can work with CMS to educate the state Medicaid agency and correct the situation.

Considerations regarding this option:

- This is the easiest way for a provider to use VFC vaccine and bill Medicaid for the administration fee.
- There are no out-of-pocket costs to the parent or guardian for the vaccine or the administration fee.

Option 2

A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

- If the primary insurer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee, up to the amount Medicaid pays for the administration fee.
- If the primary insurer denies payment of vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC borrowing form.

Considerations regarding this option:

- The provider may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
- The provider should choose from the vaccine inventory that is most cost-effective for the family.
- The parent/guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Appendix D: Patient Eligibility Screening Record

Vaccines for Children (VFC) Program
Patient Eligibility Screening Record

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office for 3 years or longer depending on state law. The record may be completed by the parent, guardian, individual of record, or by the health care provider. VFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure the child's eligibility status has not changed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine. Providers using a similar form (paper-based or electronic) must capture all reporting elements included in this form.

1. Child's Name :_____
   Last Name First Name MI
2. Child's Date of Birth: __ __/__ __/__ __ __ __
3. Parent/Guardian/Individual of Record:_____
   Last Name First Name MI
4. Primary Provider's Name:_____
   Last Name First Name MI
5. To determine if a child (0 through 18 years of age) is eligible to receive federal vaccine through the VFC and state programs, at each immunization encounter/visit enter the date and mark the appropriate eligibility category. *If Column A-D is marked, the child is eligible for the VFC program. If column E, F or G is marked the child is not eligible for federal VFC vaccine.*

	Eligible for VFC Vaccine				Not eligible for VFC Vaccine		
	A	B	C	D	E	F	G
Date	**Medicaid Enrolled**	**No Health Insurance**	**American Indian or Alaskan Native**	***Underinsured** served by FQHC, RHC or deputized provider	**Has health insurance that covers vaccines**	****Other underinsured**	*****Enrolled in CHIP (CoverTN)**

**Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance. In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate underinsured children.*

*** Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.*

****Children enrolled in separate state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.*

CDC FORM-2014

Please Note: In Tennessee the Local Health Departments are the only deputized providers. CDC form is available at: https://www.tn.gov/content/dam/tn/health/documents/immunizationrequirements/Patient_Eligibility_Screening_Record.pdf

Appendix E: Vaccine Borrowing Form

Facility Name:
Pin #:

VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7Other or 13Other) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code		Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1		VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2		VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3		Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4		Short-dated VFC dose was exchanged with private dose	11
Accidental use of VFC dose for a private patient	5		Accidental use of a Private dose for a VFC eligible patient	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6		Other – Describe:	13Other
Other – Describe:	7Other			

WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and made available to the State/Local or Territorial Immunization Program upon request.

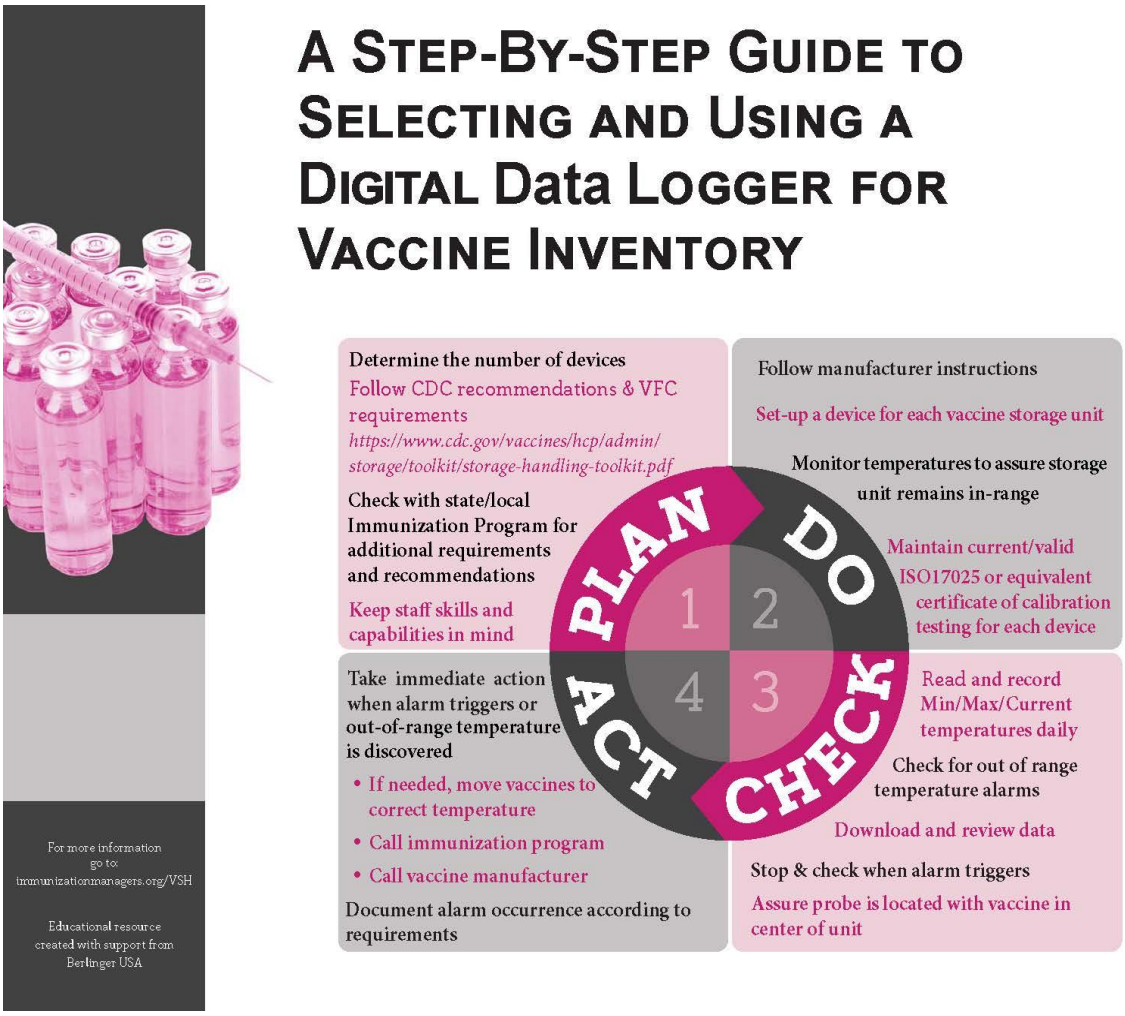
1

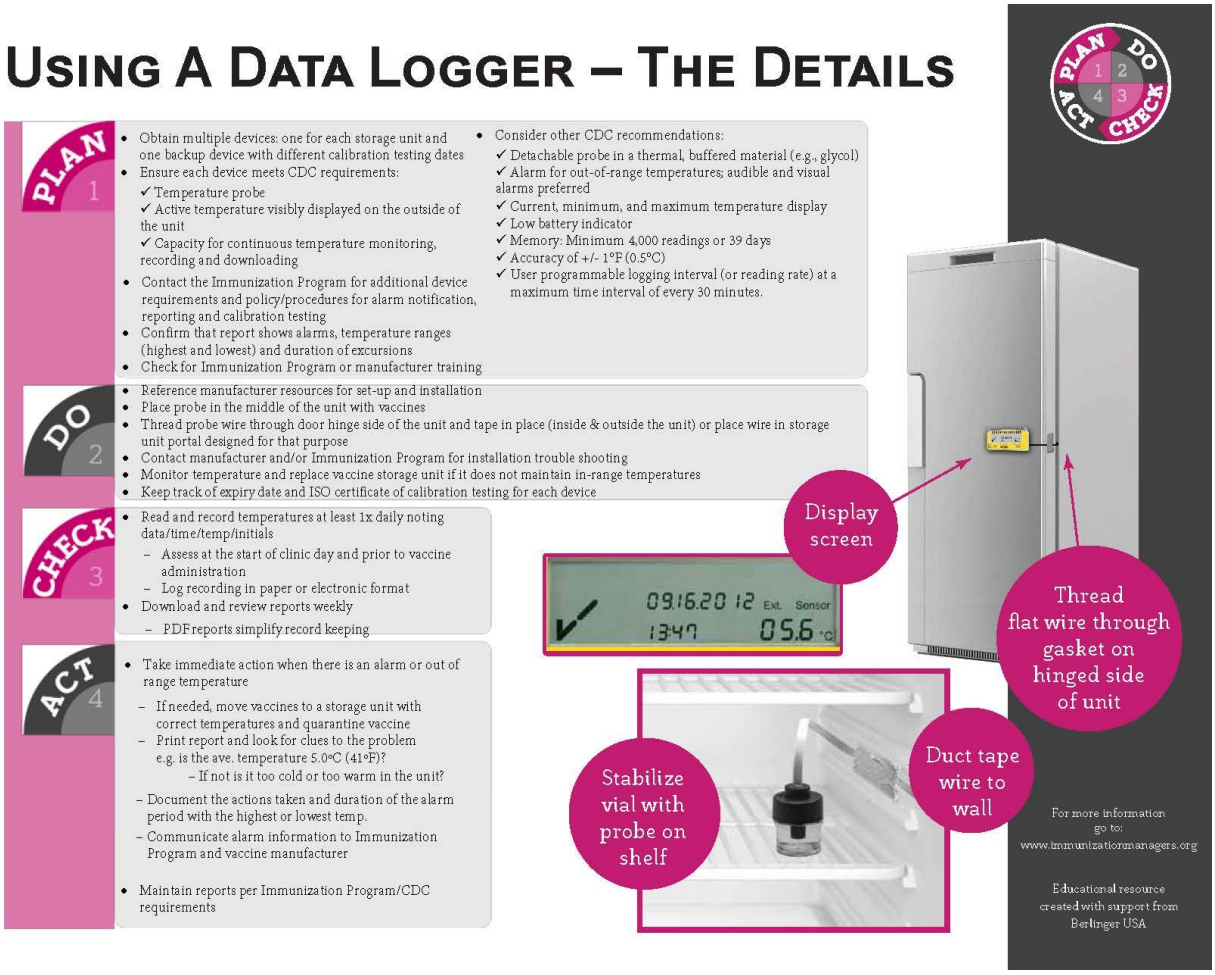
Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): ____/____/_____ **to** ____/____/_____

VACCINE BORROWING REPORT TABLE						
A Vaccine Type Borrowed	**B** Stock Used (VFC or Private)	**C** Patient Name	**D** Patient DOB (XX/XX/XXXX)	**E** Date Dose Administered (XX/XX/XXXX)	**F** Reason Appropriate Vaccine Stock was not Used (Use legend code on page 1 to mark one reason for each dose borrowed)	**G** Date Dose Returned to Appropriate Stock (XX/XX/XXXX)
I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.						
Provider Name:			Provider Signature:			Date:

2

Appendix F: Guide to Selecting a Digital Data Logger





Can be found on the Association of Immunization Managers website: http://c.ymcdn.com/sites/www.immunizationmanagers.org/resource/resmgr/virt_exhibt_hall/Fridge-tag_Data_Logger_Flyer.pdf (last accessed 1/18/2018)

Appendix G: Packing Vaccines for Emergency Transport

Be prepared for vaccine transport. Commercially available vaccine transport options are available at a variety of price points and may be preferred. However, the protocol below is designed to safely store vaccines for hours at proper temperatures using readily available materials.

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.

Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Distributed by

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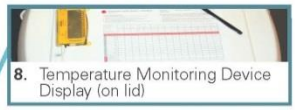
Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.


8. Temperature Monitoring Device Display (on lid)

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

Available at: http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf (last accessed 1/12/2018)

Appendix H: Mobile Immunization Clinic Log

Mobile Immunization Clinic Log

Clinic Date	Clinic Location	VFC Vaccine Type	VFC Vaccine Amount	Private Vaccine Type	Private Vaccine Amount

Appendix I: Hourly Temperature Logs

Tennessee Immunization Program (TIP)

Hourly Vaccine Temperature Log – Celsius Refrigerated

Refrigerated vaccines must be maintained between 2ºC and 8ºC.

Call TIP immediately if vaccine is exposed to temperature below 2ºC for more than 15 minutes or above 8ºF for more than 60 minutes. Take the below actions:

1. Label vaccine "do not use"
2. Store vaccine under proper conditions as quickly as possible
3. Notify TIP at 1-800-404-3006

Date: _____ **Location:** _____

Time Vaccine Placed into Unit: _____ **Temperature:** _____

Time Vaccine Removed from Unit: _____ **Temperature:** _____

Time	AM/PM	Temperature	Initials

Date: _____ **Time:** _____

VFC Coordinator Signature: _____

Prior to the vaccine being returned to the clinic, the VFC Coordinator must review temperature logs to verify vaccine cold chain has been maintained; attach this log to the data logger report.

Tennessee Immunization Program
710 James Robertson Parkway Nashville, TN 37243 **1-800-404-3006**

Tennessee Immunization Program (TIP)

Hourly Vaccine Temperature Log – Celsius Freezer

Frozen vaccine must be maintained between -50ºC and -15ºC.

Call TIP immediately if vaccine is exposed to temperature above -15ºC for more than 60 minutes. Take the below actions:

1. Label vaccine "do not use"
2. Store vaccine under proper conditions as quickly as possible
3. Notify TIP at 1-800-404-3006

Date: _____ **Location:** _____

Time Vaccine Placed into Unit: _____ **Temperature:** _____

Time Vaccine Removed from Unit: _____ **Temperature:** _____

Time	AM/PM	Temperature	Initials

Date: _____ **Time:** _____

VFC Coordinator Signature: _____

Prior to the vaccine being returned to the clinic, the VFC Coordinator must review temperature logs to verify vaccine cold chain has been maintained; attach this log to the data logger report.

Tennessee Immunization Program
710 James Robertson Parkway Nashville, TN 37243 **1-800-404-3006**